Harvard Pilgrim Health Care

***Medical Review Criteria Lyme/Tick-Borne Diseases- IV Antibiotic Use***

# STRIDEsm (HMO) MEDICARE ADVANTAGE

**Effective Date: January 1, 2017**

**Subject: Lyme/Tick-Borne Diseases- IV Antibiotic Use**

**Policy:**

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage covers intravenous (IV) antibiotics that are medically necessary and clinically indicated for treatment of Lyme and other Tick-Borne Diseases (i.e., Human Granulocytic Anaplasmosis, Babesiosis).

- Covered antibiotics include Ceftriaxone, Cefotaxime, or Penicillin G (as appropriate).
- Use of IV Imipenem-Cilastatin, Ceftazidime, Cefuroxime, Vancomycin, Bicillin, Ampicillin, Azithromycin is not clinically indicated for the treatment of early or late disseminated stages of Lyme disease.

Covered services must be:

- Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member's medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.[1]

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover the use of IV antibiotics for treatment of nonspecific, noninflammatory musculoskeletal complaints/arthalgias or fatigue, or in situations where evidence of Lyme Borrelia infection is based on unvalidated tests. (Such use is not clinically indicated.)

- In addition, Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover the extended use of IV antibiotics (i.e., course of treatment that exceeds the timeframes described below) for

[1] Appropriate accrediting organizations include the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), or another Centers for Medicare and Medicaid Services (CMS) Approved Accrediting Organization.

treatment of any Tick-Borne Disease as there is insufficient evidence that such use is clinically indicated.

**Authorization:**
Prior authorization is required for all IV antibiotic treatment of Lyme and Tick-Borne Diseases provided in outpatient, office, or home settings.

- Documentation including history and results of testing from all prior treatment for Tick-Borne Disease(s) must be submitted.

**Criteria:**

- **Lyme Disease**
  Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage authorizes up to 30 consecutive days of treatment with IV Ceftriaxone, Cefotaxime, or Penicillin G when:
  1. Diagnosis is confirmed by positive Lyme-specific IgG Western blot on two tier testing[2], and clearly documented in the medical record; AND
  2. Clinical documentation confirms the member meets the parameters for any of the conditions listed below.

| Condition: | Parameters: |
|---|---|
| **Lyme Meningitis** | Medical record documentation confirms ALL the following:<br>1. Clinical features of meningitis (e.g., acute headache, photosensitivity, nuchal rigidity, fever);<br>2. Positive Lyme specific IgM Western blot on two tier testing, with or without IgG positivity[3];<br>3. Other causes of meningitis have been evaluated and determined to be less likely;<br>4. CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, and normal glucose.<br>▪ Requirement for CSF findings may be waived if spinal tap is refused or contraindicated. |
| **Lyme Cranial Neuritis** | Medical record documentation confirms ALL the following: |

[2] IgG is considered positive only when 5/10 of the following kDa bands are seen: 18,23,28,30,39,41,45,58,66,93. IgM is considered positive only when the IgM is performed **within 4 weeks** of illness onset, and when 2/3 of the following kDa bands are seen; 23, 39, 41.

[3] For the small proportion of patients who have negative or indeterminate IgM positivity, and suspicion remains high repeat testing 2-4 weeks later should be performed. With high clinical suspicion treatment with IV antibiotics will not be delayed for these results.

| Condition: | Parameters: |
|---|---|
| | 1. Unilateral or bilateral cranial nerve affected (facial palsy is most common);<br>2. Other causes of cranial nerve palsy have been evaluated and determined to be less likely;<br>3. CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, normal glucose.<br>▪ Requirement for CSF findings may be waived if spinal tap is refused or contraindicated.) |
| **Lyme Radiculoneuritis or Mononeuritis Multiplex** | Medical record documentation confirms ALL the following:<br>1. Clinical exam and/or EMG/NCS documents findings of ANY of the following:<br>a. Singular or multiple root involvement with motor, sensory, and reflex changes in a physiologic pattern;<br>b. Axonal changes on EMG/NCS<br>c. Findings of mononeuritis multiplex on EMG/NCS, consistent with clinical history and exam<br>2. Other causes of radiculoneuritis or mononeuritis multiplex have been evaluated and are less likely;<br>3. CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, normal glucose.<br>▪ Requirement for CSF findings may be waived if spinal tap is refused or contraindicated. |
| **Lyme Carditis** | Medical record documentation confirms ANY of the following:<br>• 1st degree AV block with PR interval >0.3 sec; or<br>• 2nd or 3rd degree block (usually managed in a monitored setting). |
| **Lyme Arthritis** | Medical record documentation confirms ALL the following:<br>1. Intermittent or persistent arthritis[4] with effusion of the knee or other large joints, and history of abrupt onset of attacks that required joint aspiration;<br>2. Joint fluid with inflammatory characteristics (i.e., polymorphonuclear predominance $\geq$ 2K cells);<br>3. Evidence that, if no neurologic involvement, two 28-day courses of oral antibiotics were used, and response was incomplete. |

[4] Other causes of monoarticular or polyarticular arthritis must have been evaluated and determined to be less likely.

| Condition: | Parameters: |
|---|---|
| **Lyme Encephalopathy** | Medical record documentation provides objective evidence of cognitive impairment (documented by a neurologist, and neuropsychiatric testing), and confirms ALL the following:<br>1. Other causes of encephalopathy have been evaluated and determined to be less likely;<br>2. CSF findings (if appropriate) of intrathecal antibody index positivity and/or elevated protein with or without a CSF pleocytosis.<br>▪ Requirement for CSF findings may be waived if spinal tap is refused or contraindicated. |
| **Lyme Encephalomyelitis**<br>▪ **European-borrelia strains** | Medical record documentation confirms ALL the following:<br>1. Presence of focal neurologic manifestations and cognitive impairment documented by objective testing and detailed mental status exam;<br>2. MRI demonstrates focal areas of inflammation with increased T2 and FLAIR signal, or enhancement with gadolinium;<br>***3.*** Other causes of encephalomyelitis have been evaluated and determined to be less likely;<br>***4.*** CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, and normal glucose.<br>▪ Requirement for CSF findings may be waived if spinal tap is refused or contraindicated. |
| **Lyme Peripheral Neuropathy** | Medical record documentation confirms ALL the following:<br>***1.*** One or more of the following:<br>▪ Symmetric distal paraesthesia (i.e., burning, tingling, numbness), multimodal sensory loss (e.g., pinprick, vibration), and mild or absent weakness/hyporeflexia<br>▪ EMG/NCS documentation of patchy axonal polyneuropathy or confluent mononeuritis multiplex;<br>***2.*** Other causes of the peripheral neuropathy have been evaluated and determined to be less likely.<br>▪ Results of Lumbar Puncture may be required (if clinically indicated) to exclude central inflammatory conditions in complex cases. Requirement may be waived if spinal tap is refused or contraindicated. |

- **<u>Human Granulocytic Anaplasmosis (HGA)</u>**

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage authorizes up to 10 days of IV doxycycline[5] when documentation confirms ALL the following:

1. Acute onset of systemic viral-like illness (e.g., fever, myalgia, headache), often in association with thrombocytopenia, leucopenia and /or elevated liver enzymes[6]; and
2. The member cannot tolerate an oral antibiotic.

- **Babesiosis**
  Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage authorizes up to 10 days of IV clindamycin[7] when documentation confirms acute onset of systemic viral-like illness (e.g., fever, myalgia, headache) and ANY of the following:
  1. Acute onset of systemic viral-like illness (e.g. fever, myalgia, headache); or
  2. Positive parasitemia on blood smear, or positive PCR amplification of babesial DNA.

**Exclusions:**

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover IV antibiotics for treatment of Lyme and other Tick-Borne Diseases when criteria above are not met.

In addition, Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover:

- IV antibiotics (e.g., Imipenem-Cilastatin, Ceftazidime, Cefuroxime, Vancomycin, Bicillin, Ampicillin, Azithromycin) for the treatment of early or late disseminated stages of Lyme disease as there is no evidence that such use is clinically indicated
- Combination antimicrobial therapy for Lyme disease
- IV antibiotics when evidence of Lyme Borrelia infection is based on unvalidated tests including (but not limited to):
  - Antigen urine assay
  - Culture, immunofluorescence staining, or cell sorting of cell wall-deficient or cystic forms of *B. burgdorferi*
  - IgM or IgG tests without a previous ELISA/EIA/IFA
  - Lymphocyte transformation tests

[5] For childen less than 8 years of age without concomitant Lyme disease, treatment is generally for 7 days, or for 3 days after resolution of fever, whichever is longer.

[6] Supportive testing would include the characteristic intragranulocytic inclusions on blood smear (wide range of positivity of 20-80%).

[7] Longer duration of antimicrobial therapy may be necessary in highly and persistently symptomatic members. IV clindamycin should be given together with oral quinine in these members.

- Measurements of antibodies in joint fluid (synovial fluid)Polymerase chain reaction (PCR) testing of either serum or urine
- Positive Western blot in the absence of a positive or equivocal other antibody test (i.e., not using two tier testing)
- Quantitative CD57 lymphocyte assays
- "Reverse Western blots"
- Western blot positivity that does not meet CDC criteria

- Less than daily use of authorized IV antibiotics
- IV antibiotics for nonspecific, noninflammatory musculoskeletal complaints/arthalgias or for fatigue

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

| HCPCS Codes | Description |
|---|---|
| **J0696** | Injection, ceftriaxone sodium, per 250 mg |
| **J0698** | Injection, cefotaxime sodium, per g |
| **J2510** | Injection, penicillin G procaine, aqueous, up to 600,000 units |
| **J2540** | Injection, penicillin G potassium, up to 600,000 units |
| | |
| **J3490** | Drugs unclassified injection |

| ICD10 Codes | Description |
|---|---|
| **A26.0** | Cutaneous erysipeloid |
| **A69.20** | Lyme disease, unspecified |
| **B60.0** | Babesiosis |
| **B99.9** | Unspecified infectious disease |
| **L53.9** | Erythematous condition, unspecified |

**Approved by UMCPC: 10/25/17**

- **Revised: 8/16; 10/17**
- **Initial Approval: 8/26/15**

**Summary of Changes**

| Date | Revision |
|---|---|
| **10/17** | Annual review and reissued |
| **9/28/16** | Delete HCPCS code (S0077)- not billable to Medicare. Add HCPCS code (J3490), and update ICD10 Code list to include Babesiosis. |
| **8/10/16** | Annual review. No substantive changes. |

**References:**


1. Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf
2. Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America (IDSA) 4/2010 at: http://www.idsociety.org/uploadedFiles/IDSA/Topics_of_Interest/Lyme_Disease/IDSALymeDiseaseFinalReport.pdf (Accessed 8/3/16).
3. The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Disease Society of America. IDSA Guidelines. CCID. 2006; 43:1089-134
4. Practice Parameter: Treatment of nervous system Lyme disease (an evidence based review): Report of Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2007; 69:91-66
5. Lyme borreliosis. Lancet 2012; 379:461-73
6. Guidelines for Laboratory Evaluation in the Diagnosis of Lyme Disease. Amer College of Physcians. Ann Int Med. 1997; 127:1106-08
7. Notice to Readers Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease. MMWR. Aug 11, 1995/ 44(31); 590-1
8. Halperin. Nervous System Lyme Disease. Infectious Disease Clinic of North America. 2008. 22: 261
9. Notice to readers: caution regarding testing for Lyme disease. MMWR, CDC Surveillance Summary, 2005, 54:125.
10. Marques A, Brown MR, Fleisher TA: Natural killer cell counts are not different between patients with post-Lyme disease syndrome and controls. Clin Vaccine Immunol 2009, 16:1249–1250.